

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Mark S. Roby

EXAMINER: B.J. Gillespie

SERIAL NO.: 10/533,041

GROUP: Art Unit 1711

FILED: December 14, 2005

DATED: December 16, 2008

TITLE: BIOABSORBABLE ADHESIVE
COMPOUNDS

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Va. 22313-1450

Filed Via EFS-Web

BRIEF ON APPEAL

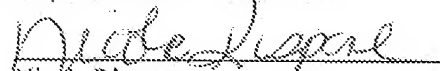
Sir;

This is an appeal from a Final Office Action dated June 17, 2008 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: December 16, 2008


Nicole Rispon

1. STATEMENT OF REAL PARTY IN INTEREST

The real party in interest for this application is United States Surgical, a Division of Tyco Healthcare Group LP.

2. STATEMENT OF RELATED CASES

Appellants, appellants' legal representative and/or the assignee of appellants' interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

3. JURISDICTIONAL STATEMENT

The present appeal is taken under 35 U.S.C. § 134(a), by applicants, whose claims have been twice rejected by the Examiner. The pending claims were finally rejected in a Final Office Action dated June 17, 2008 (the "Final Office Action"). A Notice of Appeal was filed on October 17, 2008, accompanied by the requisite fees under 37 CFR § 41.20(b)(1). An extension of time to file the Notice of Appeal under 37 CFR § 1.136(a) was filed with and accompanied the Notice of

Appl. No. 10/533,041
Brief on Appeal dated December 16, 2008
Reply to Final Office Action mailed June 17, 2008

Appeal on October 17, 2008. The present Appeal Brief is being filed on the date noted on the first page of this Appeal Brief, i.e., December 16, 2008.

4. TABLE OF CONTENTS

1. STATEMENT OF REAL PARTY IN INTEREST	2
2. STATEMENT OF RELATED CASES	2
3. JURISDICTIONAL STATEMENT	2
5. TABLE OF AUTHORITIES	5
7. STATUS OF AMENDMENTS	6
8. GROUNDS OF REJECTION TO BE REVIEWED	6
9. STATEMENT OF FACTS	8
10. ARGUMENT	11
A. English Fails to Render Obvious the Claimed Compositions and Methods	12
1. English fails to Render Obvious the Claimed Compositions	12
2. English fails to Render Obvious the Claimed Methods.....	15
B. English In View of Bennett Fails to Render Obvious the Claimed Methods	16
C. Lipatova In View of English and Further In view of Ueyanagai Fail to Render Obvious the Claimed Compositions and Methods	18
1. Lipatova, English, and/or Ueyanagai fail to Render Obvious the Claimed Compositions.....	18
2. Lipatova, English, and/or Ueyanagai fail to Render Obvious the Claimed Methods.....	25
F. Conclusion.....	29
11. APPENDIX.....	31
A. CLAIMS SECTION.....	31
B. CLAIMS SUPPORT AND DRAWING ANALYSIS SECTION	39
C. MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION.....	42
D. EVIDENCE SECTION.....	43
E. RELATED CASES SECTION	44

5. TABLE OF AUTHORITIES

Statutes

35 U.S.C. § 134(a).....	2
35 U.S.C. §103	11
35 U.S.C. §103(a).....	passim
37 C.F.R. §41.20 (b)(2).....	1
37 CFR § 1.136(a).....	2
37 CFR § 41.20(b)(1).....	2

Cases

<u>In re Gorman</u> , 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).....	27
<u>In re Rouffet</u> , 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).....	29

6. [RESERVED]

7. STATUS OF AMENDMENTS

The Advisory Action mailed August 25, 2008 (the “Advisory Action”) indicated that a Response to Final Office Action filed on August 11, 2008 had been considered but failed to place the application in condition for allowance.

8. GROUND OF REJECTION TO BE REVIEWED

The following issues are on appeal:

whether the compositions and methods of claims 1-6, 8-9, 15-18, 20-22, and 24 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 4,804,691 to English et al. (“English”), which discloses provides an adhesive formed by reacting a biodegradable monomer with a polyhydroxy polymerization initiator in the presence of a catalyst and preparing a diisocyanate-terminated prepolymer adhesive by reacting the resulting hydroxyl-terminated polyester with excess aromatic diisocyanate, but nowhere discloses or suggests the use of di- and tri-functional compounds;

whether the method of claim 23 is obvious under 35 U.S.C. §103(a) over English in view of U.S. Patent No. 6,339,130 to Bennett et al. (“Bennett”), which

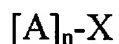
discloses star polymers endcapped with isocyanates, but nowhere discloses the recited composition including its 3 components; and

whether the compositions and methods of claims 1-9, 13-22 and 24 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 4,057,535 to Lipatova et al. (“Lipatova”), which discloses an adhesive including aromatic diisocyanates, macrodiisocyanates of a defined formula, and 2,4,6-tris(dimethylaminomethyl)phenol, but nowhere discloses a trifunctional compound that is end-capped with an aromatic diisocyanate (including bioabsorbable polyesters and trifunctional adducts of the aromatic polyisocyanate), in view of English, and further in view of U.S. Patent No. 4,388,245 to Ueyanagai et al. (“Ueyanagai”), which discloses processes for preparing modified aliphatic, alicyclic, or araliphatic organic polyisocyanates, but nowhere teaches or suggests a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, nor teaches or suggests applying such a composition to tissue.

9. STATEMENT OF FACTS

Independent claim 1 is directed to a composition including a bioabsorbable oligomeric compound (*see, e.g.*, Specification page 3, lines 5-6) that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 4, line 22 to page 5, line 4), a trifunctional compound that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7), and an aromatic diisocyanate (*see, e.g.*, Specification page 7, lines 18-21).

Independent claim 19 is directed to a composition including a bioabsorbable oligomeric compound (*see, e.g.*, Specification page 3, lines 5-6) that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 4, line 22 to page 5, line 4), wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone (*see, e.g.*, Specification page 3, lines 10-17), n is from about 1 to about 6 (*see, e.g.*, Specification page 3, line 14) and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol,

1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid (*see, e.g.*, Specification page 3, line 18 to page 4, line 7); a trifunctional compound that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7), wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols (*see, e.g.*, Specification page 5, lines 18-22); and an aromatic diisocyanate (*see, e.g.*, Specification page 7, lines 18-21) selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene (*see, e.g.*, Specification page 5, lines 1-4).

Independent claim 20 is directed to a method including applying to tissue (*see, e.g.*, Specification page 3, lines 1-3; page 8, lines 10-12; page 9, lines 3-11) a composition comprising a bioabsorbable oligomeric compound (*see, e.g.*, Specification page 3, lines 5-6) that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 4, line 22 to page 5, line 4); a trifunctional compound that is end-capped with an aromatic diisocyanate (*see, e.g.*, Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7); and an aromatic diisocyanate (*see, e.g.*, Specification page 7, lines 18-21); and crosslinking the composition (*see, e.g.*, Specification page 8, lines 6-23).

Nowhere does English disclose or suggest the use of tri-functional compounds that correspond to those claimed by applicants. (See Office Action mailed June 6, 2007 at page 4, lines 13-14.)

Nowhere does English teach polyesters based on a mixture of di- and tri-functional compounds. (See Office Action mailed February 6, 2008 at page 3, lines 7-9.)

Nowhere does Lipatova disclose tri-functional compounds that correspond to those claimed by applicants. (See Office Action mailed June 6, 2007 at page 4, lines 13-14; Office Action mailed February 6, 2008 at page 5, lines 1-2.)

Bennett notes that certain aromatic diisocyanates are to be avoided in its compositions due to toxicity concerns. (See Office Action mailed June 6, 2007 at page 6, lines 7-8; Office Action mailed February 6, 2008 at page 4, lines 3-4.)

10. ARGUMENT

In rejecting the present claims under 35 U.S.C. §103, the Examiner has misconstrued the art cited against the pending claims and failed to establish that the references render obvious the pending claims. Moreover, the Examiner has failed to establish a prima facie case of obviousness and has utilized applicants' own disclosure, plus impermissible hindsight, to suggest the pending claims are obvious (see Amendment After Final submitted August 11, 2008, at page 10, lines 12-16.)

The patentability of four groups of claims are separately argued herein, namely: (1) claims 1-9, and 13-14, which generally recite compositions including a bioabsorbable oligomer, a trifunctional compound, and an aromatic diisocyanate; (2) claims 15-18 and 21-24, which generally recite methods for adhering tissue surfaces, methods for adhering surgical devices to tissue, and methods for sealing defects in tissue with compositions including a bioabsorbable oligomer, a trifunctional compound, and an aromatic diisocyanate; (3) claim 19, which generally recites a composition including a bioabsorbable oligomeric compound of the structure $[A]_n-X$, in combination with a trifunctional compound selected from a

specific group of compounds, and an aromatic diisocyanate; and (4) claim 20, which generally recites a method including applying to tissue a composition comprising a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate; a trifunctional compound that is end-capped with an aromatic diisocyanate; and an aromatic diisocyanate; and crosslinking the composition.

**A. English Fails to Render Obvious
the Claimed Compositions and Methods**

The Examiner has rejected claims 1-6, 8-9, 15-18, 20-22, and 24 as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 4,804,691 to English et al. (“English”). (See Office Action mailed February 6, 2008 at page 2, ¶3.)

1. English fails to Render Obvious the Claimed Compositions

With respect to the rejection of claims 1-6, and 8-9 under 35 U.S.C. §103(a) as obvious over English, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. (See Amendment filed May 5, 2008 at page 10, lines 12-16.)

English provides an adhesive formed by reacting a biodegradable monomer with a polyhydroxy polymerization initiator in the presence of a catalyst and preparing a diisocyanate-terminated prepolymer adhesive by reacting the resulting hydroxyl-terminated polyester with excess aromatic diisocyanate. While the prepolymer may be utilized as a single-component or two-component system, nowhere is there any teaching or suggestion in English of a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. (Id. at page 10, line 17 to page 11, line 3.) Where the prepolymer is utilized as a single-component system, the diisocyanate is reacted with the hydroxyl-terminated polyester, whereupon the resulting isocyanate prepolymer is applied to soft tissue, with water from the soft tissue forming carbon dioxide and an amine. The amine may then react with another isocyanate group to promote chain growth and cross linking through urea linkages. Where a two-component system is utilized, the components are kept separate until just prior to use, with the hydroxyl-terminated prepolymer combined with the diisocyanate just prior to application to tissue. (See Amendment After Final submitted August 11, 2008 at page 9, line 22 to page 10, line 7.)

As admitted by the Examiner, nowhere does English disclose or suggest the use of di- and tri-functional compounds. (See Office Action mailed June 6, 2007 at page 4, lines 13-14; Office Action mailed February 6, 2008 at page 3, lines 7-9.) The Examiner then states it would be obvious to combine two compositions to form a third composition. (See Office Action mailed February 6, 2008 at page 3, ¶4.) However, claim 1 requires 3 components: a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. (See Amendment mailed May 5, 2008 at page 11, lines 8-11.)

As previously noted, nowhere is there any teaching or suggestion in English of a composition including a bioabsorbable oligomeric compound that is end-capped with 3 components, (Id. at page 11, lines 11-13) namely an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. The recited compositions include 3 components; English only possesses, at most, 2. (See Amendment After Final submitted August 11, 2008 at page 10, line 12.) The Examiner has thus failed to establish a *prima facie* case of obviousness and is using applicants' own disclosure, plus impermissible hindsight, to suggest that it would be obvious to modify English to include all 3 components in its "single

component” or “two-component” systems. (See Amendment After Final submitted August 11, 2008 at page 10, lines 12-16.) Thus, English cannot render claim 1 obvious, nor claims 2-6 and 8-9, which depend directly or indirectly from claim 1 and incorporate all of its limitations therein.

2. English fails to Render Obvious the Claimed Methods

With respect to the rejection of claims 15-18, 20-22, and 24 under 35 U.S.C. §103(a) as obvious over English, claims 15-18, 21-22 and 24 all depend, directly or indirectly, from claim 1 and include methods for utilizing the recited compositions for adhering tissue surfaces, methods for adhering surgical devices to tissue, and methods for sealing defects in tissue. While English discloses methods for making biodegradable adhesives for soft tissue, as noted above, nowhere does English disclose or suggest the compositions of the recited claims, including the 3 recited components, and thus cannot render obvious the methods of claims 15-18, 21-22 and 24.

With respect to claim 20, English nowhere discloses or suggests a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an

aromatic diisocyanate, and crosslinking the composition. (See Amendment submitted May 5, 2008 at page 11, lines 16-20.) As noted above with respect to claim 1, nowhere does English disclose or suggest applying to a tissue a composition including the 3 separate components, i.e., a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. (Id. at page 11, line 20 to page 12, line 3.) Without such teaching or suggestion, English cannot render claim 20 obvious.

**B. English In View of Bennett
Fails to Render Obvious the Claimed Methods**

With respect to the rejection of claim 23 under 35 U.S.C. §103(a) as obvious over English in view of U.S. Patent No. 6,339,130 to Bennett et al. ("Bennett"), claim 23 depends from claim 17 which, in turn, depends from claim 1. Claim 17 recites a method for sealing a defect in tissue with a composition of claim 1, and claim 23 recites crosslinking the composition at temperatures from about 20°C to about 40°C for a time of from about 30 seconds to about 1 hour. As described above, English does not render claim 1 obvious. Bennett fails to remedy the deficiencies of English, no matter how these references may be combined.

Nowhere does Bennett disclose a composition including a bioabsorbable

oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. (See Amendment filed May 5, 2008 at page 12, lines 10-13.) While Bennett's star polymers may be endcapped with isocyanates, there is no disclosure of the recited composition including its 3 components. (See Amendment After Final submitted August 11, 2008 at page 11, lines 13-14.) Moreover, as noted by the Examiner, Bennett specifies that the selection of diisocyanate is important and that certain aromatic diisocyanates should not be employed due to toxicity concerns. (See Office Action mailed June 6, 2007 at page 6, lines 7-8; Office Action mailed February 6, 2008 at page 4, lines 3-4.) That Bennett may use similar cure characteristics and catalysts does not alter the fact that it does not disclose or suggest the recited **compositions**. (See Amendment After Final submitted August 11, 2008 at page 11, lines 15-16.) Thus, Bennett cannot render obvious the pending claims, and it is respectfully submitted that claim 23 is patentable over English and Bennett, no matter how these references may be combined.

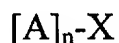
**C. Lipatova In View of English and Further In view of Ueyanagai
Fail to Render Obvious the Claimed Compositions and Methods**

The Examiner has rejected claims 1-9, 13-22 and 24 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,057,535 to Lipatova et al. ("Lipatova"), in view of English, and further in view of U.S. Patent No. 4,388,245 to Ueyanagai et al. ("Ueyanagai"). (See Office Action mailed February 6, 2008 at page 4, ¶8.)

**1. Lipatova, English, and/or Ueyanagai fail to
Render Obvious the Claimed Compositions**

With respect to the rejection of claims 1-9, and 13-14 under 35 U.S.C. §103(a) as obvious over Lipatova in view of English and further in view of Ueyanagai, nowhere does Lipatova disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. (See Amendment filed May 5, 2008 at page 12, lines 16-21.)

Similarly, nowhere does Lipatova disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-

isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19. (Id. at page 13, line 4 to page 14, line 5.)

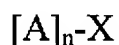
Rather, Lipatova discloses an adhesive including aromatic diisocyanates, macrodiisocyanates of a defined formula, and 2,4,6-tris(dimethylaminomethyl)phenol. Nowhere in Lipatova is there any teaching or suggestion of a trifunctional compound that is end-capped with an aromatic diisocyanate. (Id. at page 14 lines 6-9.) In fact, as admitted by the Examiner, Lipatova does not disclose bioabsorbable polyesters and trifunctional adducts of the aromatic polyisocyanate. (See Office Action mailed June 16, 2007 at page 4, lines 13-14; Office Action mailed February 6, 2008 at page 5, lines 1-2.) Without such disclosure, Lipatova cannot anticipate or render obvious the compositions of the pending claims, including independent claims 1 and 19. As claims 2-9, and 13-14 all depend, directly or indirectly, from claim 1 and incorporate all of its limitations therein, Lipatova similarly cannot render obvious those claims.

English fails to remedy the deficiencies of Lipatova, no matter how these references may be combined. As noted above, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-

capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1.

(See Amendment filed May 5, 2008 at page 14, lines 16-20.)

Similarly, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



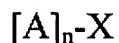
wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-

ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19. (Id. at page 15, line 3 to page 16, line 4.)

Uenayagi similarly fails to remedy the deficiencies of Lipatova and English, no matter how these references may be combined. Nowhere does Uenayagi disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. (Id. at page 16, lines 11-15.)

Moreover, nowhere does Uenayagi disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an

aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-

aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19. (Id. at page 17, line 1 to page 18, line 2.)

While Uenayagi discloses processes for preparing modified aliphatic, alicyclic, or araliphatic organic polyisocyanates, which include prepolymers that may be dimers, trimers, tetramers, pentamers, or mixtures thereof, its processes include heating a polyisocyanate having at least two isocyanate groups in the presence of a diisocyanate monomer to form the modified polyisocyanate. Nowhere is there any teaching or suggestion of a composition including the three components recited in claims 1 and 19, namely, a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. (Id. at page 18, lines 3-11.) Moreover, the compositions of Uenayagi are utilized as coating materials, non-yellowing foams, and non-yellowing adhesives (see, e.g., Uenayagi at column 3, lines 17-25). (See

Amendment After Final submitted August 11, 2008 at page 17, lines 12-14.)

Nowhere does Uenayagi appreciate the desirability of bioabsorbable components.

Thus, at least for the foregoing reasons, neither Lipatova, English, nor Uenayagi, taken alone or in any combination, render any of the composition claims obvious, including the compositions of claims 1-9, and 13-14.

**2. Lipatova, English, and/or Ueyanagai fail to
Render Obvious the Claimed Methods**

With respect to the rejection of the methods of claims 15-18, 21-22 and 24, under 35 U.S.C. §103(a) as obvious over Lipatova in view of English and further in view of Ueyanagai, claims 15-18, 21-22 and 24 all depend, directly or indirectly, from claim 1 and include methods for utilizing the recited compositions for adhering tissue surfaces, methods for adhering surgical devices to tissue, and methods for sealing defects in tissue. As to the methods disclosed in 15-18, 21-22 and 24, as noted above, nowhere does Lipatova, English or Ueyanagai disclose or suggest the recited compositions or utilizing the compositions as adhesives in vivo as recited in the claims.

With respect to the method of claim 20, nowhere does Lipatova disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic

diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition as recited in claim 20. (See Amendment submitted May 5, 2008 at page 12, line 21 to page 13, line 3.) Rather, Lipatova discloses an adhesive including aromatic diisocyanates, macrodiisocyanates of a defined formula, and 2,4,6-tris(dimethylaminomethyl)phenol. Nowhere in Lipatova is there any teaching or suggestion of a trifunctional compound that is end-capped with an aromatic diisocyanate. (Id. at page 14, lines 6-9.)

In addition, nowhere does English disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition as recited in claim 20. (Id. at page 14, line 20 to page 15, line 2.)

Similarly, nowhere does Uenayagi disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic

diisocyanate, and crosslinking the composition as recited in claim 20. (Id. at page 16, lines 16-20.)

As noted above, nowhere is there any teaching or suggestion in English of a composition including the 3 separate components recited in claims 1 and 19 or methods of applying such compositions to tissue as recited in claims 20 and 15-18 and 21-22. (Id. at page 16, lines 5-10; new argument with respect to 15-18 and 21-22.)

The Examiner has taken the position that Lipatova and English are analogous art and cannot be attacked individually, as the rejection is based on the combination of references; (see Office Action mailed June 17, 2008 at page 8, ¶18) however, there must be some teaching, suggestion, motivation, or similar reason for one skilled in the art to combine the references as suggested by the Examiner. “It is impermissible, however, to simply engage in a hindsight reconstruction of the claimed invention, using applicant’s structure as a template and selecting elements from references to fill the gaps.” In re Gorman, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Here, English does not provide the recited multi-component composition; neither does Lipatova. Moreover, Lipatova’s composition, as noted above, is not bioabsorbable. Thus, for at least the foregoing reasons, one skilled in the art would not look to combine the two references as suggested by the Examiner; the

Examiner has engaged in impermissible hindsight reconstruction. Thus neither reference, taken alone or in any combination, renders obvious the pending claims.

Moreover, as to Uenauagi, nowhere is there any teaching or suggestion of applying such a composition to tissue as recited in claim 20. (See Amendment filed May 5, 2008 at page 18, lines 11-12.) Without such teaching or suggestion, Uenayagi fails to remedy the deficiencies of Lipatova and/or English, no matter how these references may be combined.

Again, there must be some teaching, suggestion or motivation to combine the references as suggested by the Examiner. As noted by the Federal Circuit,

The Board did not, however, explain what specific understanding or technical principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead the board merely invoked the high level of skill in the field of the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard

against hindsight analysis and rote application of the legal test for obviousness.

In re Rouffet, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

One skilled in the art would not look to combine Lipatova, English and Uenayagi as suggested by the Examiner. The Examiner has engaged in impermissible hindsight in taking the applicants' own disclosure to provide the suggestion for combining the references and rejecting the claims. (See Amendment after Final submitted on August 11, 2008 at page 17, lines 19-22.) Thus, claims 1-9, 13-22 and 24 are patentable over Lipatova, English, and/or Uenayagi, and withdrawal of this rejection is respectfully requested.

F. Conclusion

In view of the foregoing, Applicant submits that independent claims 1, 19 and 20 are not rendered obvious by English, Lipatova, and/or Ueyanagai, whether taken alone or in any combination, and that claim 23 is not rendered obvious by English and/or Bennett. Moreover, as claims 2-9, 13-18, 21-22 and 24 all depend directly or indirectly from claim 1 and incorporate all of the limitations of claim 1 therein and any intervening claim, they similarly are not obvious over English, Lipatova, and/or Ueyanagai, whether taken alone or in any combination. Thus, all

Appl. No. 10/533,041
Brief on Appeal dated December 16, 2008
Reply to Final Office Action mailed June 17, 2008

of the claims pending in this application, namely claims 1-9, and 13-24, are in
condition for allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael R. Brew", is written over a horizontal line.

Michael R. Brew
Reg. No. 43,513
Attorney for Applicants

CARTER, DELUCA, FARRELL & SCHMIDT, LLP
445 Broad Hollow Road - Suite 420
Melville, New York 11747
(631) 501-5700
(631) 501-3526 (fax)
mbrew@cdfsllaw.com

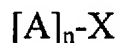
MRB/nr

11. APPENDIX

A. CLAIMS SECTION

1. (Original) A composition comprising:
a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate;
a trifunctional compound that is end-capped with an aromatic diisocyanate;
and
an aromatic diisocyanate.

2. (Previously presented) The composition as in claim 1 wherein the bioabsorbable oligomeric compound is a compound having the structure:



wherein A is a bioabsorbable group, n is from 1 to about 6 and X is a residue from a multifunctional initiator.

3. (Previously presented) The composition as in claim 2 wherein the bioabsorbable group is a group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone.

4. (Previously presented) The composition as in claim 2 wherein X is a residue from a multifunctional initiator selected from the group consisting of diols, aromatic and alkyl triols, polyols, alcohol amines, dicarboxylic acids and aromatic dicarboxylic acids.

5. (Previously presented) The composition as in claim 2 wherein X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, neopentyl glycol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid.

6. (Previously presented) The composition as in claim 1 wherein the bioabsorbable oligomer is end-capped with an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene.

7. (Previously presented) The composition as in claim 1 wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols.

8. (Previously presented) The composition as in claim 1 wherein the trifunctional compound is end-capped with an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene.

9. (Previously presented) The composition as in claim 1 wherein the aromatic diisocyanate is selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene.

Claims 10-12 (canceled)

13. (Previously presented) The composition as in claim 1 wherein the bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate is present in an amount from about 50 to about 95 percent by weight of the composition;

the trifunctional compound that is end-capped with an aromatic diisocyanate is present in an amount from about 5 to about 40 percent by weight of the composition; and

the aromatic diisocyanate is present in an amount from about 1 to about 10 percent by weight of the composition.

14. (Previously presented) The composition as in claim 1 wherein the bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate is present in an amount from about 70 to about 90 percent by weight of the composition;

the trifunctional compound that is end-capped with an aromatic diisocyanate is present in an amount from about 8 to about 25 percent by weight of the composition; and

the aromatic diisocyanate is present in an amount from about 2 to about 5 percent by weight of the composition.

15. (Previously presented) A method of adhering first and second tissue surfaces, the method comprising approximating the first and second tissue surfaces; and applying to the approximated tissue surfaces a composition of claim 1.

16. (Previously presented) A method of adhering a surgical device to tissue, the method comprising: applying to the surgical device a composition of claim 1; and contacting the surgical device with tissue.

17. (Previously presented) A method of sealing a defect in tissue, the method comprising identifying a tissue site containing a defect; and applying a composition of claim 1 to the site of the defect.

18. (Previously presented) A method for reducing leakage of bodily fluids or air comprising applying to a tissue defect a composition in accordance with claim 1 and crosslinking the composition.

19. (Previously presented) A composition comprising:
a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-

methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene.

20. (Previously presented) A method comprising: applying to tissue a composition comprising a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate; a trifunctional compound that is end-capped with an

aromatic diisocyanate; and an aromatic diisocyanate; and crosslinking the composition.

21. (Previously presented) The method as in claim 17 wherein crosslinking comprises contacting the composition with a compound selected from the group consisting of water, diethylene glycol and polyethylene glycol.

22. (Previously presented) The method as in claim 17 wherein crosslinking includes the use of a catalyst.

23. (Previously presented) The method as in claim 17 wherein crosslinking is conducted at temperatures from about 20° C. to about 40 ° C. for a time from about thirty seconds to about one hour.

24. (Previously presented) The method as in claim 17 wherein the composition is crosslinked prior to application to tissue.

B. CLAIMS SUPPORT AND DRAWING ANALYSIS SECTION

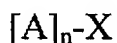
1. (Original) A composition comprising:

a bioabsorbable oligomeric compound {*see, e.g.*, Specification page 3, lines 5-6} that is end-capped with an aromatic diisocyanate { *see, e.g.*, Specification page 4, line 22 to page 5, line 4};

a trifunctional compound that is end-capped with an aromatic diisocyanate {*see, e.g.*, Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7}; and
an aromatic diisocyanate {*see, e.g.*, Specification page 7, lines 18-21}.

19. (Previously presented) A composition comprising:

a bioabsorbable oligomeric compound {*see, e.g.*, Specification page 3, lines 5-6} that is end-capped with an aromatic diisocyanate {*see, e.g.*, Specification page 4, line 22 to page 5, line 4}, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and ϵ -caprolactone {*see, e.g.*, Specification page 3, lines 10-17}, n is from about 1 to about 6 {*see, e.g.*, Specification page 3, line 14} and

X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid {*see, e.g., Specification page 3, line 18 to page 4, line 7*}; a trifunctional compound that is end-capped with an aromatic diisocyanate {*see, e.g., Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7*}, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols {*see, e.g., Specification page 5, lines 18-22*}; and an aromatic diisocyanate {*see, e.g., Specification page 7, lines 18-21*} selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-

methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene *{see, e.g., Specification page 5, lines 1-4}*.

20. (Previously presented) A method comprising: applying to tissue *{see, e.g., Specification page 3, lines 1-3; page 8, lines 10-12; page 9, lines 3-11}* a composition comprising a bioabsorbable oligomeric compound *{see, e.g., Specification page 3, lines 5-6}* that is end-capped with an aromatic diisocyanate *{see, e.g., Specification page 4, line 22 to page 5, line 4}*; a trifunctional compound that is end-capped with an aromatic diisocyanate *{see, e.g., Specification page 5, line 18 to page 6, line 9; page 7, lines 2-7}*; and an aromatic diisocyanate *{see, e.g., Specification page 7, lines 18-21}*; and crosslinking the composition *{see, e.g., Specification page 8, lines 6-23}*.

Appl. No. 10/533,041
Brief on Appeal dated December 16, 2008
Reply to Final Office Action mailed June 17, 2008

C. MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION

None

Appl. No. 10/533,041
Brief on Appeal dated December 16, 2008
Reply to Final Office Action mailed June 17, 2008

D. EVIDENCE SECTION

None

Appl. No. 10/533,041
Brief on Appeal dated December 16, 2008
Reply to Final Office Action mailed June 17, 2008

E. RELATED CASES SECTION

None